

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MASSACHUSETTS

3
4 IN RE: NEW ENGLAND : MDL No. 2419

5 COMPOUNDING PHARMACY, INC. : Docket No.:

6 PRODUCTS LIABILITY LITIGATION: 1:13-md-2419(RWZ)

7 -----:

8 This document relates to: :

9 :
10 ARNETTA, ET AL v. BOX HILL :

11 SURGERY CENTER, LLC, ET AL :

12 No. 1:14-cv-14022-RWZ :

13 :
14 BOWMAN, ET AL v. BOX HILL :

15 SURGERY CENTER, LLC, ET AL :

16 No. 1:14-cv-14028-RWZ :

17 :
18 DAVIS, ET AL v. BOX HILL :

19 SURGERY CENTER, LLC, ET AL :

20 No. 1:14-cv-14033-RWZ :

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1 DREISCH, ET AL v. BOX HILL :
2 SURGERY CENTER, LLC, ET AL :
3 No. 1:14-cv-14029-RWZ :
4 :
5 FARTHING, ET AL v. BOX HILL :
6 SURGERY CENTER, LLC, ET AL :
7 No. 1:14-cv-14036-RWZ :
8 :
9 KASHI, ET AL v. BOX HILL :
10 SURGERY CENTER, LLC, ET AL :
11 No. 1:14-cv-14026-RWZ :
12 :
13 TORBECK, ET AL v. BOX HILL :
14 SURGERY CENTER, LLC, ET AL :
15 No. 1:14-cv-14023-RWZ :
16 :
17 HANDY, ET AL v. BOX HILL :
18 SURGERY CENTER, LLC, ET AL :
19 No. 1:14-cv-14019-RWZ :

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Deposition of STEVEN PAUL COHEN, M.D.,
was taken via Veritext Virtual on Wednesday, March
1, 2017, commencing at 10:10 a.m., at Pessin Katz
Law, P.A., 10500 Little Patuxent Parkway, Suite
650, Columbia, Maryland, before MICHELE D. LAMBIE,
Notary Public.

ALSO PRESENT; Ashley E. Geno, Esquire
(via telephone)

Reported By:

Michele D. Lambie, CSR-RPR

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<p>1 I'm looking for published data that have reported 2 the development of arachnoiditis in an epidural 3 injection that was not intrathecal. 4 A. Yes, and I just gave you a recent one 5 from 2013 with a caudal injection. And, again, the 6 reason that that's important is because the, the 7 length that separates where the caudal injection is 8 administered and where the dura ends, and piercing 9 the dura is what makes an injection intrathecal, is 10 several centimeters, so it would be almost 11 impossible to accidentally make a caudal epidural 12 injection go intrathecal. So, in other words, 13 there's something else that, that caused this 14 medication to go intrathecal and create 15 arachnoiditis. 16 Q. Okay. And that case report that you've 17 described, do you know offhand where it is 18 published? 19 A. Asian Spine Journal. 20 Q. And if I write to Mr. Kirby and ask him 21 for the quote, you'll be able to give it to him?</p>	<p>1 it's a preservative or whether it's the steroid 2 itself that causes some of these complications? 3 A. Right. There are, there are 4 literature -- there is literature in very, very 5 well-regarded journals that are peer reviewed that 6 say, you know, it's not the preservative, and then 7 you have, you know, literature in outstanding, you 8 know, journals, such as Lancet Oncology, BMJ, 9 Medical journal of Australia that say, yes, it is 10 the preservative, and no amount of benzyl alcohol 11 or other preservatives are safe. 12 MR. KIRBY: Objection to form. 13 BY MR. ROTH: 14 Q. You mentioned Depo-Medrol, and I will 15 read the transcript -- strike that. 16 Was there any other preservative-free MPA 17 that was available to Dr. Bhambhani before the 18 outbreak, other than Depo-Medrol by commercial 19 manufacturers? 20 A. So I, I don't know the answer. I know 21 that there are other forms of -- so you have, you</p>
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<p>1 A. Yes. He'll, he'll be able to give that, 2 and, and there are a few others. One in, you know, 3 Review of Neurology. Like I said, not every, you 4 know, complication gets published. So in my 5 experience -- 6 Q. I understand. 7 A. Yeah. 8 Q. I mean, I understand that. I'm looking 9 for the ones that, you know, that are available. 10 Can you tell me whether or not in those case 11 reports the cause of the arachnoiditis had been 12 determined? In other words, did they say that's 13 the preservative? 14 A. Yes. It was deemed to be caused 15 by -- well, by the, you know, by the medication, 16 and I believe it was Depo-Medrol. And how can you 17 say, you know, what component of the Depo-Medrol, 18 you know, was responsible for arachnoiditis? No 19 one can say that. 20 Q. Am I correct that in the medical 21 literature that there is debate about what, whether</p>	<p>1 know, Depo-methylprednisolone acetate. You have 2 Depo-methylprednisolone succinate, and, you know, I 3 don't know what was and was not available, or even 4 if it was available, whether or not there were 5 shortages of certain, you know, drugs at the time 6 of 2012/2013. 7 Q. But, again, whether there were shortages 8 or not, you're not going to offer an opinion that 9 Dr. Bhambhani's decision to use NECC's MPA was 10 based upon a drug shortage, correct? 11 A. I don't know what the basis, you know, 12 for her decision was besides what I read, you know, 13 in her deposition. 14 Q. Is polyethylene glycol associated with 15 any risks to patients who undergo epidurals? 16 MR. KIRBY: Objection to form. 17 THE WITNESS: Yeah. It, it may affect 18 nerve conduction, you know, when injected around 19 nerves. Like I say, you know, any of these 20 medications can elicit an inflammatory reaction 21 that can result in perhaps arachnoiditis in</p>

<p style="text-align: right;">Page 98</p> <p>1 susceptible patients.</p> <p>2 BY MR. ROTH:</p> <p>3 Q. Is polyethylene glycol a, is it</p> <p>4 characterized as a preservative?</p> <p>5 A. Yes.</p> <p>6 Q. Doctor, I mentioned earlier that we had</p> <p>7 been given, we received an email from Mr. Kirby's</p> <p>8 office yesterday with a drop box of material. Can</p> <p>9 you tell me -- it says, materials that were sent to</p> <p>10 Dr. Cohen. Did you do independent research for</p> <p>11 purposes of this case, other than reviewing</p> <p>12 materials that were sent to you by Mr. Kirby's law</p> <p>13 firm?</p> <p>14 A. You know, I pulled out some abstracts,</p> <p>15 you know, when I wanted a question answered, but</p> <p>16 like I said, you know, I speak on epidural steroid</p> <p>17 injections all the time. So sometimes it's</p> <p>18 difficult to distinguish, you know, where I</p> <p>19 obtained, you know, information or what was the</p> <p>20 reason for me looking this, looking up the answer</p> <p>21 to a certain question. But, yes, I'm sure that I</p>	<p style="text-align: right;">Page 100</p> <p>1 Now, I don't know whether you have the</p> <p>2 capacity to be looking at that now, whether that's</p> <p>3 what you're looking at?</p> <p>4 MR. KIRBY: He is.</p> <p>5 THE WITNESS: Yes, I am.</p> <p>6 BY MR. ROTH:</p> <p>7 Q. So my question to you is, Are these</p> <p>8 articles that were given to you or that you sent to</p> <p>9 Mr. Kirby's office?</p> <p>10 A. I sent those articles to Mr. Kirby's</p> <p>11 office.</p> <p>12 Q. To be clear so that we know what we're</p> <p>13 talking about, the first article is by</p> <p>14 Dr. Manchikanti, the first two actually are written</p> <p>15 by him.</p> <p>16 MR. KIRBY: Yeah. Hey, Harry, I can</p> <p>17 shortcut this if you want to make it easier.</p> <p>18 MR. ROTH: Yes.</p> <p>19 MR. KIRBY: He didn't send, he didn't</p> <p>20 send the Manchikanti ones. I think my paralegal</p> <p>21 just included them because they came from the last</p>
<p style="text-align: right;">Page 99</p> <p>1 did do some research specifically for this case,</p> <p>2 including, you know, finding out which journals it</p> <p>3 was mentioned that these preservatives might be</p> <p>4 associated with neurotoxicity, finding out the</p> <p>5 reports of arachnoiditis, you know, in response to</p> <p>6 medications that were deemed to actually be</p> <p>7 epidural and not intrathecal.</p> <p>8 Q. There is a series of folders in this drop</p> <p>9 box, one of which is called, Literature - Concern</p> <p>10 for Preservation. First of all, did you receive a</p> <p>11 drop box of material from Mr. Kirby's law firm?</p> <p>12 A. You know, honestly nothing personal, I</p> <p>13 received too many drop boxes from Mr. Kirby's law</p> <p>14 firm. It would be hard to, to say which, you know,</p> <p>15 which one, but, yes, I received many.</p> <p>16 Q. And I guess -- and we'll do this in a</p> <p>17 follow-up question. In the drop box I received</p> <p>18 yesterday, and, again, it's called Materials</p> <p>19 Sent to Dr. Cohen, one of the folders is called</p> <p>20 Literature - Concern For Preservation, and there</p> <p>21 are six articles that are included in that folder.</p>	<p style="text-align: right;">Page 101</p> <p>1 deposition, but --</p> <p>2 MR. ROTH: Well, let --</p> <p>3 MR. KIRBY: He can answer though.</p> <p>4 MR. ROTH: Thank you.</p> <p>5 BY MR. ROTH:</p> <p>6 Q. What I'm trying to discern, Dr. Cohen, is</p> <p>7 what information was provided to you by Mr. Kirby's</p> <p>8 office and whether you can tell us what information</p> <p>9 was a byproduct of your research for this case?</p> <p>10 A. So I --</p> <p>11 Q. And -- okay. Go ahead.</p> <p>12 A. So all of the articles that I'm looking</p> <p>13 at here I read and provided, except for -- so this</p> <p>14 one I was very familiar with. So the one article</p> <p>15 by Manchikanti and Falco, I was familiar with, but</p> <p>16 I think Dr. Kirby, Mr. Kirby sent that to me, but I</p> <p>17 had read this article already.</p> <p>18 MR. KIRBY: That's the one, just for the</p> <p>19 record, at the top it says, Safeguards to Prevent</p> <p>20 Neurologic Complications.</p> <p>21 MR. ROTH: Okay.</p>

<p style="text-align: right;">Page 122</p> <p>1 the literature and expertise, are these</p> <p>2 complications that you've described, either steroid</p> <p>3 psychosis or impairment of wound healing or</p> <p>4 bleeding, caused by preservatives that are in</p> <p>5 steroids or by the steroid medication itself?</p> <p>6 A. They would be caused by the steroid</p> <p>7 medication itself if -- and, again, you are</p> <p>8 correct, this is a big if, I can't see a way, but</p> <p>9 the only way that it, that they could result</p> <p>10 possibly from preservatives is if for some reason</p> <p>11 preservatives, you know, increased the</p> <p>12 bioavailability, and then you would -- in essence,</p> <p>13 you would be seeing a higher dose. Your receptors</p> <p>14 would be seeing more, and you might be more likely</p> <p>15 to develop steroid-related side effects or</p> <p>16 complications.</p> <p>17 Q. Have you seen any study, data,</p> <p>18 information that preservatives, in fact, increase</p> <p>19 bioavailability that would increase the dose of the</p> <p>20 drug?</p> <p>21 A. I don't believe there's any evidence to</p>	<p style="text-align: right;">Page 124</p> <p>1 safer for her patients than steroids that contained</p> <p>2 preservatives?</p> <p>3 MR. KIRBY: Objection to form and</p> <p>4 foundation. You can answer.</p> <p>5 THE WITNESS: I saw nothing that she</p> <p>6 indicated in her deposition to that effect.</p> <p>7 BY MR. ROTH:</p> <p>8 Q. Now, I'm not trying to be duplicative.</p> <p>9 My first set of questions were related to the</p> <p>10 choice of preservative versus preservative free,</p> <p>11 and now I want to ask about NECC and the decision</p> <p>12 to purchase from NECC.</p> <p>13 Can you describe what you will testify to</p> <p>14 as the reason why Dr. Bhambhani ordered steroids</p> <p>15 from NECC?</p> <p>16 MR. KIRBY: Objection to form and</p> <p>17 foundation.</p> <p>18 THE WITNESS: So I -- it really depends</p> <p>19 on the, you know, the questions that are asked. So</p> <p>20 I can testify as to why a reasonable doctor might</p> <p>21 want to order from there, and I can just testify to</p>
<p style="text-align: right;">Page 123</p> <p>1 support that. I also don't believe it's been</p> <p>2 examined, but you're probably right. I -- that's</p> <p>3 just one possible theoretical explanation, and it's</p> <p>4 probably not true.</p> <p>5 Q. Is that explanation -- okay. You've</p> <p>6 answered my question. Is that explanation</p> <p>7 something that you would be able to testify to to a</p> <p>8 reasonable degree of medical certainty?</p> <p>9 A. Definitely not.</p> <p>10 Q. All right. In your review of</p> <p>11 Dr. Bhambhani's, the medical records relating to</p> <p>12 Dr. Bhambhani's patients at Box Hill, did you see</p> <p>13 any evidence that her patients had any adverse</p> <p>14 response to epidurals given before the outbreak?</p> <p>15 A. No.</p> <p>16 Q. Is there a difference in the -- well,</p> <p>17 strike that.</p> <p>18 Did you -- other than conversations with</p> <p>19 her mentor and her prior use, was there anything</p> <p>20 else that you will describe that Dr. Bhambhani did</p> <p>21 to determine that preservative-free steroids were</p>	<p style="text-align: right;">Page 125</p> <p>1 what I've read in Dr. Bhambhani's deposition where</p> <p>2 she said it's to avoid some of the side effects</p> <p>3 that, that she experienced with, with, you know,</p> <p>4 branded Depo-Medrol and her past good experiences</p> <p>5 with, with the NECC compound.</p> <p>6 BY MR. ROTH:</p> <p>7 Q. All right. So my question was related to</p> <p>8 not what any doctor would do, but Dr. Bhambhani,</p> <p>9 and other than her past experience, is there</p> <p>10 anything else that you learned from her deposition</p> <p>11 or from anything that you reviewed regarding why</p> <p>12 she selected NECC to purchase MPA for her steroids?</p> <p>13 A. Just the ones that we've discussed.</p> <p>14 Q. You used the phrase on page 8 of your</p> <p>15 report -- it's just a short one. You talk about</p> <p>16 the absence of guidelines and information. You</p> <p>17 used the phrase, Box Hill's due diligence prior to</p> <p>18 purchasing from NECC.</p> <p>19 Can you tell me what specific things, if</p> <p>20 there's anything else than what we have discussed,</p> <p>21 that comprise Box Hill's due diligence for</p>

<p style="text-align: right;">Page 126</p> <p>1 purchasing from NECC?</p> <p>2 A. You know, as we agreed, Dr. Bhambhani did</p> <p>3 not review the specific documents from NECC,</p> <p>4 although if she had, that would have certainly been</p> <p>5 very reassuring.</p> <p>6 So the main reason that she did from Box</p> <p>7 Hill was based on eight to nine years of</p> <p>8 experience, of very good experience without the</p> <p>9 same complications using that drug.</p> <p>10 Q. You testified earlier that you're not</p> <p>11 the, you have not in your military or civilian</p> <p>12 experience been the person who determines where to</p> <p>13 purchase medications from. You understand</p> <p>14 Dr. Bhambhani had that responsibility for Box Hill,</p> <p>15 correct?</p> <p>16 A. Yes, she did, and this is not going to</p> <p>17 affect -- I just want to be, you know, truthful</p> <p>18 here in case you look. So at Johns Hopkins for</p> <p>19 medications, such as the liquid capsaicin that I</p> <p>20 brought up, I do determine where we buy that</p> <p>21 from --</p>	<p style="text-align: right;">Page 128</p> <p>1 But for the other one, for, you know,</p> <p>2 capsaicin, there's been, which we do inject just</p> <p>3 like, you know, steroids, no one has ever gone to</p> <p>4 inspect the facility, but what they do is they</p> <p>5 review all of the documents.</p> <p>6 They look at, you know, someone from</p> <p>7 pharmacy, so not for us, and we use this, and this</p> <p>8 just really recently happened.</p> <p>9 So for many years, this was not done</p> <p>10 before. For about ten years, but after the</p> <p>11 outbreak, they started to review the documents, but</p> <p>12 they have not inspected that place, even though</p> <p>13 that place is in, is in Maryland.</p> <p>14 Q. So, first of all, the inspections that</p> <p>15 were done by Hopkins of the facility, did that take</p> <p>16 place before or after the outbreak?</p> <p>17 A. So there are two places of -- there are,</p> <p>18 there are two compounding pharmacies that produce</p> <p>19 product that we use in the pain center. For one of</p> <p>20 them, Hopkins has inspected them before. It's not</p> <p>21 annually. It may be every several years, and that</p>
<p style="text-align: right;">Page 127</p> <p>1 Q. Okay.</p> <p>2 A. -- and that's just, you know, really</p> <p>3 specific instances.</p> <p>4 Q. When you purchase that -- and that's</p> <p>5 stuff you purchase from a compound pharmacy,</p> <p>6 correct?</p> <p>7 A. Yes, here in Maryland.</p> <p>8 Q. Right. When you purchase that, do you</p> <p>9 have, do you purchase that as an inventory that is</p> <p>10 stored, or is that something you purchase via a</p> <p>11 patient-specific prescription?</p> <p>12 A. So I can tell you the practices of our</p> <p>13 pain medicine treatment, and this has gone through,</p> <p>14 you know, the committee that oversees all</p> <p>15 medications that are used as well as the pharmacy.</p> <p>16 So the, the medications that we, that we</p> <p>17 purchase that are from compounding pharmacies</p> <p>18 include intrathecal steroids, and once every two</p> <p>19 years, someone from Johns Hopkins goes down, who is</p> <p>20 a pharmacologist, and inspects that institution,</p> <p>21 and they look at all of the documents.</p>	<p style="text-align: right;">Page 129</p> <p>1 place is in Florida.</p> <p>2 For the other one, which we've been using</p> <p>3 for more than ten years, no one has ever inspected</p> <p>4 that place, but after the outbreak, the people from</p> <p>5 pharmacy reviewed the documents, including from the</p> <p>6 Maryland Board of Pharmacy, and said, This is okay</p> <p>7 to inject in your patients.</p> <p>8 Q. Before the outbreak, did the people from</p> <p>9 pharmacy review the documents for that local</p> <p>10 compounding pharmacy?</p> <p>11 A. They did not. This was -- they, they</p> <p>12 brought this up after the outbreak so that this</p> <p>13 would not happen to Johns Hopkins.</p> <p>14 Q. Before the outbreak with the compounding</p> <p>15 pharmacy that was in Florida, do I understand that</p> <p>16 that was inspected and documents were reviewed by</p> <p>17 the Hopkins pharmacy folks?</p> <p>18 A. So the, the inspections were definitely</p> <p>19 not every year. They were -- there was at least</p> <p>20 one inspection, I know that --</p> <p>21 Q. Okay.</p>

<p style="text-align: right;">Page 130</p> <p>1 A. -- for the one in Florida.</p> <p>2 Q. And the one inspection, you mean before</p> <p>3 the outbreak?</p> <p>4 A. Correct.</p> <p>5 Q. So we got to this because I asked whether</p> <p>6 or not you were writing patient prescriptions for</p> <p>7 the liquid medication that was obtained from the</p> <p>8 Maryland compounding pharmacy, and then you</p> <p>9 described what the Hopkins pharmacy folks do.</p> <p>10 A. So what --</p> <p>11 Q. Do you write the prescriptions? And if</p> <p>12 you do, do you write them to Hopkins, or do you</p> <p>13 write them to the compounding pharmacy itself?</p> <p>14 A. So this is complicated, but -- actually,</p> <p>15 it's not, but it's a little bit different. We give</p> <p>16 the patient a written prescription, and then they</p> <p>17 bring it to the pharmacy, they fill it, and then</p> <p>18 they bring it back to Johns Hopkins.</p> <p>19 Q. When you say they take it to the</p> <p>20 pharmacy, you mean the compounding pharmacy that's</p> <p>21 in Maryland?</p>	<p style="text-align: right;">Page 132</p> <p>1 Q. In other words, he's still a physician</p> <p>2 whose work you respect and whose research you</p> <p>3 continue to or articles you continue to look at?</p> <p>4 A. Yes. I still cite some of his, his</p> <p>5 articles in my work.</p> <p>6 Q. I'd like you to -- I'd like to turn to</p> <p>7 page, to Exhibit 13, please. No. I'm sorry,</p> <p>8 Exhibit 15.</p> <p>9 MR. KIRBY: Okay. We have it.</p> <p>10 MR. ROTH: Thank you.</p> <p>11 BY MR. ROTH:</p> <p>12 Q. For some reason -- wait a minute. The</p> <p>13 page I want you to look at is the fifth page. For</p> <p>14 some reason -- I'm sorry, the fourth page. I don't</p> <p>15 see a Bates stamp on it, but it's the May 18th</p> <p>16 prescription order form. Can you turn to that,</p> <p>17 please?</p> <p>18 MR. KIRBY: This is it I think. We've</p> <p>19 got it.</p> <p>20 MR. ROTH: All right.</p> <p>21 BY MR. ROTH:</p>
<p style="text-align: right;">Page 131</p> <p>1 A. Yes.</p> <p>2 Q. And then they bring the substance, the</p> <p>3 medication back, and then you inject it?</p> <p>4 A. Correct, so in a sealed, in a sealed</p> <p>5 vial.</p> <p>6 Q. Right. Is that something that -- is that</p> <p>7 the process that was done before the outbreak as</p> <p>8 well?</p> <p>9 A. For one of the -- yeah, for the one that</p> <p>10 we -- for -- yes, for the one in Maryland.</p> <p>11 Q. I can't remember what it's called, but</p> <p>12 that's the liquid stuff, the liquid medication you</p> <p>13 were describing?</p> <p>14 A. Yes.</p> <p>15 Q. By the way, we were talking a lot about</p> <p>16 Dr. Manchikanti. Your decision to not continue</p> <p>17 with the Interventional Pain Society that he</p> <p>18 started, did that have anything to do with his</p> <p>19 qualifications as a pain management physician or a</p> <p>20 doctor in any way?</p> <p>21 A. No.</p>	<p style="text-align: right;">Page 133</p> <p>1 Q. Doctor, you've seen this before, correct?</p> <p>2 A. Yes, I have seen this.</p> <p>3 Q. Have you ever ordered any medication in</p> <p>4 the, in the form that Dr. Bhambhani described with</p> <p>5 NECC?</p> <p>6 MR. KIRBY: Objection to form and</p> <p>7 foundation. You can answer.</p> <p>8 THE WITNESS: No. I would never have had</p> <p>9 a reason since I don't order my medications from</p> <p>10 NECC.</p> <p>11 BY MR. ROTH:</p> <p>12 Q. How about from any medical either</p> <p>13 manufacturer or compounder?</p> <p>14 A. So you don't even need prescriptions</p> <p>15 for medications when you order from a manufacturer,</p> <p>16 and for the, the few patients where we order from</p> <p>17 compounding, you know, pharmacies, unlike steroids</p> <p>18 in which everyone gets the same dose in the same</p> <p>19 concentration, the prescriptions or the medications</p> <p>20 that we use, you know, from compounding pharmacies,</p> <p>21 such as for intrathecal steroids, are different for</p>

<p style="text-align: right;">Page 134</p> <p>1 every single patient, so they have to be prepared 2 specially.</p> <p>3 Q. I'm sorry, I missed that last part of 4 that. I apologize.</p> <p>5 A. So unlike steroids where every patient, 6 you know, basically gets the same preparation, 7 usually the same dose in the same form, for the 8 medications, the few medications that we order from 9 compounding pharmacies, everybody gets a different 10 mixture; therefore, they have to be ordered 11 separately by individual prescriptions.</p> <p>12 Q. Are you aware before the outbreak of any 13 rules and regulations that dictate how a physician 14 is to order medications that are compounded by a 15 pharmacy?</p> <p>16 MR. KIRBY: Objection to form and 17 foundation. You can answer.</p> <p>18 THE WITNESS: Before this outbreak, I was 19 not aware of, of those regulations. Those 20 regulations are really directed towards, towards 21 pharmacies, and I have enough --</p>	<p style="text-align: right;">Page 136</p> <p>1 as, you know, at Walter Reed. That information is 2 not, is never included in any lectures nor are 3 there any lectures at conferences.</p> <p>4 It's not -- before 2013, it was not 5 mentioned in articles or textbooks, so I would say 6 that it was not standard of care at that time, and 7 it may not be even standard of care at this time.</p> <p>8 BY MR. ROTH:</p> <p>9 Q. How did you learn how to write 10 prescriptions?</p> <p>11 A. I learned back in probably, you know, 12 internship from another doctor, maybe from a 13 resident.</p> <p>14 Q. Did you come to learn from reading 15 materials in this case how it is that Dr. Bhambhani 16 would order steroids from NECC?</p> <p>17 A. Yes.</p> <p>18 Q. What did you learn?</p> <p>19 A. That she sent NECC, because of their 20 requirements per the Federal Food Drug, Food, Drug, 21 and Cosmetic Act of 1938, because of NECC's</p>
<p style="text-align: right;">Page 135</p> <p>1 BY MR. ROTH:</p> <p>2 Q. Well, is that something --</p> <p>3 A. Sure.</p> <p>4 Q. I'm sorry, Doctor.</p> <p>5 A. I was saying I have enough difficulty 6 keeping up with all of the regulations that are 7 directed towards medical doctors.</p> <p>8 Q. Would you agree that the standard of care 9 would require a physician who is prescribing 10 medication to know the rules and regulations that 11 would apply to them in, in completing those 12 prescriptions?</p> <p>13 MR. KIRBY: Objection to form and 14 foundation.</p> <p>15 THE WITNESS: So I would say that that's 16 not standard of care because most people did not 17 know that before 2013.</p> <p>18 Also, as the, you know, head of the 19 division at Johns Hopkins, we probably have the, 20 the strongest didactic teaching program for any 21 pain medicine fellowship in the world, and as well</p>	<p style="text-align: right;">Page 137</p> <p>1 requirements, she gave them past patient lists of 2 patients that she anticipated would have epidural 3 steroid injections. She sent those to the, to the 4 pharmacy, and they, in turn, sent back medications, 5 and all of the medications were the same.</p> <p>6 Q. Where did you -- I'm sorry. I thought 7 you were finished.</p> <p>8 A. I was just saying, and that she ordered 9 some 1 cc and 5 cc's vials and 40 and 80 milligrams 10 per cc, but aside from those minor differences, all 11 of the medications that she used were the same. 12 And I learned about her practices from, you know, 13 from actually reviewing the records.</p> <p>14 Q. Do you -- I'm sorry. Every time I'm 15 about to ask you a question, it sounds like you're 16 going to add something.</p> <p>17 A. No. No. No. Ask.</p> <p>18 Q. Where did you learn that the requirement 19 that she provide a patient list came from the FDA?</p> <p>20 A. I think I had been reading material 21 pertaining to this case. It might have been a</p>

<p style="text-align: right;">Page 142</p> <p>1 you order it from, you know, Pfizer or, or Upjohn</p> <p>2 because they're the same, and it was the same for</p> <p>3 ordering the steroids from NECC. They were the</p> <p>4 same for every single patient. So why do you need</p> <p>5 an individual prescription?</p> <p>6 Q. When you say they're the same, the</p> <p>7 specifications for them are identical, correct?</p> <p>8 A. Correct. So it doesn't matter what</p> <p>9 patient --</p> <p>10 Q. Let me --</p> <p>11 A. Yeah.</p> <p>12 Q. So, but there could be a difference in</p> <p>13 the way that a compounding pharmacy manufactures</p> <p>14 something versus an FDA approved manufacturer,</p> <p>15 isn't that true?</p> <p>16 MR. KIRBY: Objection.</p> <p>17 THE WITNESS: In the way that they</p> <p>18 manufacture, there could be. I'm not an expert in,</p> <p>19 you know, in manufacturing, but what I would say is</p> <p>20 that, is that just like Pfizer was sending out</p> <p>21 identical 1 cc vials of Depo-Medrol, NECC was</p>	<p style="text-align: right;">Page 144</p> <p>1 There are 14 states that have laws against</p> <p>2 homosexuality. There are many states that have</p> <p>3 laws against adultery, but I can tell you that I've</p> <p>4 never seen a police officer prosecuting, you know,</p> <p>5 anyone, let alone another police officer because</p> <p>6 someone was committing, you know, adultery.</p> <p>7 So, you know, it's the same thing for</p> <p>8 immigration. You know, people have to figure out</p> <p>9 what's important, what's the intent of the law and</p> <p>10 deciding to enforce this.</p> <p>11 FDA knew, and the Massachusetts Board of</p> <p>12 Pharmacy knew what was being done, and they</p> <p>13 continued to allow them to do this. Therefore,</p> <p>14 they obviously thought that it's not a danger to</p> <p>15 public safety.</p> <p>16 Q. Okay. So what I'm trying to get to is,</p> <p>17 and you have taken us a little bit far afield, is</p> <p>18 this requirement, this FDA requirement that you say</p> <p>19 NECC had to get prescriptions, and I'm looking for</p> <p>20 the source of that requirement. Can you tell me</p> <p>21 what it is --</p>
<p style="text-align: right;">Page 143</p> <p>1 sending out to hundreds of people who use them</p> <p>2 identical vials of, you know, 5 cc, 1 cc steroids;</p> <p>3 therefore, that really negates the, the very reason</p> <p>4 that you would need an individual prescription.</p> <p>5 BY MR. ROTH:</p> <p>6 Q. Well, then why did NECC request it?</p> <p>7 A. So the Act is, as you know, is, you know,</p> <p>8 80 years old, and at the time, it was very</p> <p>9 relevant. If anyone would comply with this, their</p> <p>10 practice would go under immediately, right, because</p> <p>11 you could never -- if someone comes in, you know,</p> <p>12 tomorrow and sees me and I say, You need an</p> <p>13 epidural steroid, if I would write a single</p> <p>14 prescription for that patient, I wouldn't be able</p> <p>15 to treat them for several months.</p> <p>16 So we know that delaying treatment is bad</p> <p>17 for patients. It's also a way to bankrupt your,</p> <p>18 you know, your practice.</p> <p>19 Look, I'm not a legal expert, and I'm not</p> <p>20 trying to say that I am, but I do know this: That</p> <p>21 there are many, many laws that are on the books.</p>	<p style="text-align: right;">Page 145</p> <p>1 A. The source was --</p> <p>2 Q. -- other than generally the FDA Act?</p> <p>3 A. So NECC, as far as I know, was complying</p> <p>4 with that 1938 Federal Food, Drug, and Cosmetic</p> <p>5 Act. What section they were complying with I</p> <p>6 couldn't tell you.</p> <p>7 Dr. Bhambhani would not be expected to,</p> <p>8 to have read that Act, just like I haven't read</p> <p>9 that Act --</p> <p>10 Q. My --</p> <p>11 A. -- because we're not, we're not</p> <p>12 pharmacists --</p> <p>13 Q. My question, Doctor, was --</p> <p>14 A. -- and she was complying with NECC's</p> <p>15 regulations requirements.</p> <p>16 Q. So the answer is you don't know the</p> <p>17 specific provision of the FDA Act that NECC was</p> <p>18 complying with --</p> <p>19 A. That is correct.</p> <p>20 Q. -- is that correct? Okay. By the way in</p> <p>21 her experience with NECC, had it always required</p>

<p style="text-align: right;">Page 154</p> <p>1 with minimizing risks. And if you read -- and</p> <p>2 actually, this is, you know, Manchikanti's</p> <p>3 infection --</p> <p>4 Q. I don't think you've answered my</p> <p>5 question.</p> <p>6 MR. KIRBY: Hold on. Hold on.</p> <p>7 BY MR. ROTH:</p> <p>8 Q. Sorry.</p> <p>9 MR. KIRBY: You can't talk over him. The</p> <p>10 court reporter is typing it down.</p> <p>11 MR. ROTH: I can, I can if it's not</p> <p>12 answering my question.</p> <p>13 MR. KIRBY: Well, just finish your answer</p> <p>14 and then you can ask him --</p> <p>15 BY MR. ROTH:</p> <p>16 Q. My question --</p> <p>17 MR. KIRBY: Just finish your answer.</p> <p>18 MR. ROTH: Well, it's not responsive to</p> <p>19 my question.</p> <p>20 THE WITNESS: Well, you asked me if I was</p> <p>21 responsible for the policy, and so --</p>	<p style="text-align: right;">Page 156</p> <p>1 Q. Correct?</p> <p>2 A. Yes, I knew.</p> <p>3 Q. All right. Am I correct -- well, I</p> <p>4 shouldn't say it this way. Would the standard of</p> <p>5 care before this outbreak require that a physician</p> <p>6 know whether or not a vial they are using for</p> <p>7 multiple patients is a single or multi-use vial?</p> <p>8 A. I think that's something that most</p> <p>9 physicians would know.</p> <p>10 Q. Because if it's a single-use vial that</p> <p>11 you're going to reuse, there are certain</p> <p>12 precautions that should be taken to maintain</p> <p>13 sterility and reduce the risk of infection for the</p> <p>14 next patient, do I understand that correctly?</p> <p>15 A. Yes.</p> <p>16 Q. Doctor, who prepared your report that you</p> <p>17 signed and it was dated October 16th, October</p> <p>18 14th --</p> <p>19 MR. KIRBY: Objection.</p> <p>20 BY MR. ROTH:</p> <p>21 Q. -- 2016?</p>
<p style="text-align: right;">Page 155</p> <p>1 BY MR. ROTH:</p> <p>2 Q. No, I did not ask that.</p> <p>3 A. -- the policy --</p> <p>4 Q. I did not ask that. I asked whether you</p> <p>5 were one of the doctors who was following the</p> <p>6 directives of the Hopkins pharmacy folks when there</p> <p>7 was this shortage?</p> <p>8 A. Yes.</p> <p>9 Q. That was the question.</p> <p>10 A. I decide whether to implement this.</p> <p>11 Q. Okay. I think you explained the policy,</p> <p>12 and I understood it. That's why I was talking over</p> <p>13 you because I didn't think you were responding to</p> <p>14 my, to the question that I asked.</p> <p>15 In those circumstances where you decided</p> <p>16 whether or not you were going to reuse a vial, you</p> <p>17 knew, did you not, whether the vial was a</p> <p>18 single-use or multi-use vial?</p> <p>19 MR. KIRBY: Objection to form. You can</p> <p>20 answer.</p> <p>21 BY MR. ROTH:</p>	<p style="text-align: right;">Page 157</p> <p>1 MR. KIRBY: Objection.</p> <p>2 THE WITNESS: So I read the, you know,</p> <p>3 the information, and we discussed this. And I said</p> <p>4 these are the important things that, that I want to</p> <p>5 be included in the report, in the report, so it was</p> <p>6 a back-and-forth, you know, process between, you</p> <p>7 know, between the editing. It went back and forth</p> <p>8 probably a half dozen times before I agreed that,</p> <p>9 before we both agreed that this was a good report.</p> <p>10 BY MR. ROTH:</p> <p>11 Q. You testified you did not read the report</p> <p>12 of Dr. Manchikanti, correct?</p> <p>13 A. Yes.</p> <p>14 Q. Did you read the report of Dr. Larkin?</p> <p>15 A. No.</p> <p>16 Q. We've talked about the need to be</p> <p>17 independent as an expert, and you agree with that,</p> <p>18 right?</p> <p>19 A. I agree.</p> <p>20 Q. And to do your own work?</p> <p>21 MR. KIRBY: Objection. I don't even know</p>

<p style="text-align: right;">Page 158</p> <p>1 what that means, but if you know, Doctor.</p> <p>2 BY MR. ROTH:</p> <p>3 Q. That you agreed, I thought, that as an</p> <p>4 expert coming into court, testifying under oath,</p> <p>5 expressing your opinion that you should be doing</p> <p>6 your own work. They should be your opinions,</p> <p>7 correct?</p> <p>8 MR. KIRBY: Well, objection to form.</p> <p>9 Whether they're his opinions or whether he did his</p> <p>10 own work, whatever that means I think is different,</p> <p>11 but if you can answer.</p> <p>12 MR. ROTH: Well, let --</p> <p>13 BY MR. ROTH:</p> <p>14 Q. Well, Dr. Cohen, do you understand -- do</p> <p>15 you understand what it means to do your own work?</p> <p>16 MR. KIRBY: Objection to form and</p> <p>17 foundation. You can answer.</p> <p>18 THE WITNESS: Yes.</p> <p>19 BY MR. ROTH:</p> <p>20 Q. You understood when you signed this</p> <p>21 report that it was going to go to lawyers like me</p>	<p style="text-align: right;">Page 160</p> <p>1 reasonable equivalent to Depo-Medrol.</p> <p>2 Now, on this report that you signed,</p> <p>3 Doctor, can you tell us please who STOPNC is?</p> <p>4 MR. KIRBY: Yeah, and I'm just going to</p> <p>5 object.</p> <p>6 MR. ROTH: Excuse me, Mr. Kirby.</p> <p>7 MR. KIRBY: No, no.</p> <p>8 MR. ROTH: You can allow the witness to</p> <p>9 answer the question.</p> <p>10 MR. KIRBY: I'm perfectly within my</p> <p>11 right --</p> <p>12 BY MR. ROTH:</p> <p>13 Q. Do you know --</p> <p>14 MR. KIRBY: I'm perfectly within --</p> <p>15 BY MR. ROTH:</p> <p>16 Q. Do you know --</p> <p>17 MR. KIRBY: Wait.</p> <p>18 MR. ROTH: Mr. Kirby, please don't --</p> <p>19 MR. KIRBY: Go ahead. Go ahead and</p> <p>20 answer the question.</p> <p>21 MR. ROTH: Please don't answer.</p>
<p style="text-align: right;">Page 159</p> <p>1 who were going to review it and then ask you a</p> <p>2 bunch of questions about it, right?</p> <p>3 A. That's right.</p> <p>4 Q. Doctor, would it surprise you to learn</p> <p>5 that there are pages of your report that contain</p> <p>6 the exact same language as the report that was</p> <p>7 submitted by Dr. Manchikanti?</p> <p>8 A. Since I read his deposition, it would</p> <p>9 not.</p> <p>10 Q. Would it surprise you, Doctor, that it's</p> <p>11 not only the exact same language, but it also</p> <p>12 includes the same typographical errors?</p> <p>13 A. I didn't know that.</p> <p>14 Q. Do you know what STOPNC is?</p> <p>15 A. No.</p> <p>16 Q. Well, do you have your report before you?</p> <p>17 A. Yeah.</p> <p>18 Q. Turn to page 11. The last sentence on</p> <p>19 page 11 reads, All of these factors support the</p> <p>20 conclusion that it was reasonable and appropriate</p> <p>21 for STOPNC to purchase compounded MPA, which is a</p>	<p style="text-align: right;">Page 161</p> <p>1 MR. KIRBY: I'm perfectly within my right</p> <p>2 to object, so go ahead and ask.</p> <p>3 MR. ROTH: You can object, but you don't</p> <p>4 need to make a speaking objection.</p> <p>5 MR. KIRBY: I can object and state my</p> <p>6 reason. Go ahead.</p> <p>7 BY MR. ROTH:</p> <p>8 Q. Who is STOPNC?</p> <p>9 MR. KIRBY: Right, and I'm objecting on</p> <p>10 the basis of Rule 26 and the privilege of</p> <p>11 protections of the drafting process. I've said</p> <p>12 before it was a typo in previous depositions. If</p> <p>13 you know who STOPNC is, then you can say.</p> <p>14 MR. ROTH: That's great. Thank you,</p> <p>15 Mr. Kirby.</p> <p>16 BY MR. ROTH:</p> <p>17 Q. Doctor, do you know --</p> <p>18 MR. KIRBY: Doctor, he can still answer</p> <p>19 the question as to whether he knows who STOPNC is.</p> <p>20 I don't know if he does or not.</p> <p>21 THE WITNESS: Box Hill Pharmacy.</p>

<p style="text-align: right;">Page 194</p> <p>1 you know, ten years ago.</p> <p>2 Q. Is it your opinion if we look at those</p> <p>3 order forms from ten years ago there's going to be</p> <p>4 no patient names?</p> <p>5 MR. KIRBY: Objection. Asked and</p> <p>6 answered. Go ahead.</p> <p>7 THE WITNESS: I don't know.</p> <p>8 BY MR. MINTZER:</p> <p>9 Q. Right. Okay. In your report on page 14</p> <p>10 at the very beginning of section 5C, it looks like</p> <p>11 VI it states, It was appropriate and in compliance</p> <p>12 with the standard of care for Box Hill to rely on</p> <p>13 the FDA, the Massachusetts Board of Registration in</p> <p>14 Pharmacy and/or the Maryland Board of Pharmacy to</p> <p>15 regulate NECC. Do you see that?</p> <p>16 MR. KIRBY: I'm sorry, where are you?</p> <p>17 THE WITNESS: Here, VI.</p> <p>18 MR. MINTZER: I'm on the doctor's report,</p> <p>19 page 14, the first full paragraph, the first</p> <p>20 sentence.</p> <p>21 MR. KIRBY: Okay.</p>	<p style="text-align: right;">Page 196</p> <p>1 information in any of the documents you have</p> <p>2 reviewed or the deposition testimony that anybody</p> <p>3 at Box Hill stated that they were relying on these</p> <p>4 entities to do anything?</p> <p>5 A. They did not --</p> <p>6 MR. KIRBY: Objection to the form.</p> <p>7 THE WITNESS: Yeah, they did not</p> <p>8 specifically cite any documents that they reviewed.</p> <p>9 BY MR. MINTZER:</p> <p>10 Q. Did anybody from Box Hill, Mr. Vickers,</p> <p>11 Dr. Bhambhani, did either one of them testify that</p> <p>12 they were relying on any agency or pharmacy board</p> <p>13 to police the drugs?</p> <p>14 MR. KIRBY: Objection to form and</p> <p>15 foundation. You can answer.</p> <p>16 THE WITNESS: They, they did not.</p> <p>17 BY MR. MINTZER:</p> <p>18 Q. Do you have any information that the</p> <p>19 Maryland Board of Pharmacy was aware back in 2012</p> <p>20 that NECC was not requiring doctors to provide</p> <p>21 individual prescriptions to patients?</p>
<p style="text-align: right;">Page 195</p> <p>1 THE WITNESS: So, yes, I, I agree with</p> <p>2 that statement a hundred percent.</p> <p>3 BY MR. MINTZER:</p> <p>4 Q. Can you direct me to any information in</p> <p>5 the case that indicates that the Box Hill</p> <p>6 Defendants were relying on the FDA, the</p> <p>7 Massachusetts Board of Registration and Pharmacy</p> <p>8 and/or the Maryland Board of Pharmacy to regulate</p> <p>9 NECC? Was there any testimony to that effect?</p> <p>10 A. The fact that they were licensed in</p> <p>11 Maryland and in Massachusetts means that those</p> <p>12 regulatory bodies did not believe that they posed a</p> <p>13 significant risk, and if the FDA believed they</p> <p>14 posed a significant risk, then they would have been</p> <p>15 remiss to not shut them down, and that may or may</p> <p>16 not have been true, but at the, at the time, you</p> <p>17 know, it wasn't.</p> <p>18 Q. I hear what you're saying, Doctor, and I</p> <p>19 understand that, and I think you have testified to</p> <p>20 that already in the deposition.</p> <p>21 My question to you is, Is there any</p>	<p style="text-align: right;">Page 197</p> <p>1 MR. KIRBY: Objection.</p> <p>2 THE WITNESS: I don't have any</p> <p>3 information to that effect.</p> <p>4 BY MR. MINTZER:</p> <p>5 Q. Again, switching gears, Doctor. Do you</p> <p>6 keep any notes related to your research for the</p> <p>7 talks that you've been asked to do related to the</p> <p>8 outbreak that you talked about earlier for some of</p> <p>9 those foreign entities or governments?</p> <p>10 A. No.</p> <p>11 Q. Do you keep copies of the talks that you</p> <p>12 give? Do you write them ahead of time?</p> <p>13 A. I have some -- I do have copies of the</p> <p>14 talks.</p> <p>15 Q. Okay. Could you provide those to</p> <p>16 Mr. Kirby so he may produce those to us in this</p> <p>17 litigation?</p> <p>18 A. You know, my FDA talk, which is very</p> <p>19 comprehensive, is probably available online.</p> <p>20 Q. I've read the FDA one. I wouldn't need</p> <p>21 that one. That's true.</p>

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<p>1 did not need to know the difference between the</p> <p>2 safety profile of drugs manufactured by a</p> <p>3 compounding pharmacy as opposed to those</p> <p>4 manufactured by, you know, an FDA manufacturer to</p> <p>5 meet the standard of care --</p> <p>6 MR. KIRBY: Objection.</p> <p>7 BY MR. ROTH:</p> <p>8 Q. -- is that right?</p> <p>9 MR. KIRBY: Objection. Asked and</p> <p>10 answered. We've been over this. Go ahead.</p> <p>11 THE WITNESS: Correct. The smartest,</p> <p>12 most knowledgeable physicians on this subject did</p> <p>13 not know this. This did not, you know, appear in</p> <p>14 the, you know, the biggest, best-selling, you know,</p> <p>15 textbooks of, of pain medicine or, or the highest,</p> <p>16 you know, the most highly cited, you know,</p> <p>17 articles.</p> <p>18 This decision just really wasn't on the</p> <p>19 radar of most pain doctors, and certainly we never</p> <p>20 taught -- we never had lectures on this topic at</p> <p>21 any institution that I've been affiliated with.</p>	<p>1 those other healthcare providers, you were just</p> <p>2 asked a series of questions, whether those other</p> <p>3 healthcare providers who you said also ordered</p> <p>4 compounded drugs or used preservative-free drugs</p> <p>5 and did what Dr. Bhambhani did, do you have an</p> <p>6 opinion whether they were reasonable healthcare</p> <p>7 providers?</p> <p>8 MR. ROTH: Objection.</p> <p>9 MR. MINTZER: Objection.</p> <p>10 MR. ROTH: Form and foundation. Do you</p> <p>11 know who they are?</p> <p>12 THE WITNESS: No, I don't know any of</p> <p>13 them by name.</p> <p>14 MR. ROTH: Okay.</p> <p>15 BY MR. KIRBY:</p> <p>16 Q. Was it unreasonable for her to order</p> <p>17 preservative-free drugs to order from NECC?</p> <p>18 A. Well, actually, I do know one person by</p> <p>19 name, but I won't mention him. No, I would say</p> <p>20 that there were -- if there were 76 people who</p> <p>21 ordered methylprednisolone from NECC and in those</p>
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<p>1 BY MR. ROTH:</p> <p>2 Q. And, again, that's specifically about the</p> <p>3 difference between compounding pharmacies and</p> <p>4 manufacturers, the FDA manufacturers?</p> <p>5 A. Right, and we're talking, again, about,</p> <p>6 you know --</p> <p>7 Q. Pre-event?</p> <p>8 A. -- yeah, pre-event.</p> <p>9 Q. Okay.</p> <p>10 MR. ROTH: Doctor, I don't have any other</p> <p>11 questions. Thank you.</p> <p>12 THE WITNESS: Thank you.</p> <p>13 MR. KIRBY: I have do have some</p> <p>14 questions. Can you deal with another ten</p> <p>15 minutes --</p> <p>16 THE WITNESS: Yeah.</p> <p>17 MR. KIRBY: -- without a break?</p> <p>18 THE WITNESS: That's fine.</p> <p>19 EXAMINATION</p> <p>20 BY MR. KIRBY:</p> <p>21 Q. Dr. Cohen, do you have an opinion whether</p>	<p>1 peoples' practice there may have been 2 or 300</p> <p>2 doctors and NECC is only one of many, many</p> <p>3 compounding pharmacies, you might conclude that</p> <p>4 there are several hundred, you know, people who are</p> <p>5 board certified or who are practicing pain who made</p> <p>6 this same decision. Are all of them bad doctors,</p> <p>7 or were they all negligent? I, I don't think</p> <p>8 that's the case.</p> <p>9 Q. You were asked about --</p> <p>10 MR. ROTH: Excuse me, Mr. Kirby. Let me</p> <p>11 just finish. Move to strike, and go ahead.</p> <p>12 BY MR. KIRBY:</p> <p>13 Q. You were also asked a lot of questions</p> <p>14 about, you know, ordering drugs from NECC in</p> <p>15 general and the safety of compounding pharmacies.</p> <p>16 Are you aware of the number of customers</p> <p>17 who ordered drugs just in general from NECC from</p> <p>18 May of 2012 to September of 2012?</p> <p>19 A. Three thousand.</p> <p>20 Q. What is that based on?</p> <p>21 A. It's based on material that I, that I</p>

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<p>1 reviewed, many pages of, of documents, and these</p> <p>2 include some of the most well-regarded and</p> <p>3 prestigious, prestigious medical institutions in</p> <p>4 the United States, such as Brigham and Women's</p> <p>5 Hospital, Yale University, Massachusetts General</p> <p>6 Hospital.</p> <p>7 Q. You were asked about whether you had any</p> <p>8 experience deciding where to purchase drugs, and I</p> <p>9 know there was a discussion in there about how</p> <p>10 Hopkins does it, but do you have experience</p> <p>11 determining which drugs to use, and -- and that's</p> <p>12 the question.</p> <p>13 MR. ROTH: Objection.</p> <p>14 THE WITNESS: Certainly --</p> <p>15 MR. ROTH: Doctor, just because I object,</p> <p>16 don't stop.</p> <p>17 THE WITNESS: Certainly as doctors if we</p> <p>18 decided that, that one medication was better than</p> <p>19 another medication, we could try to undergo the</p> <p>20 process by which the medications are, are changed</p> <p>21 and -- but in terms of who to purchase it from,</p>	<p>1 Q. Through your review of the records and</p> <p>2 his deposition, do you know what type of steroid</p> <p>3 he, he uses when he does injections?</p> <p>4 A. I believe that he said he uses</p> <p>5 triamcinolone.</p> <p>6 Q. Do you agree with the use of</p> <p>7 triamcinolone?</p> <p>8 MR. ROTH: Objection.</p> <p>9 MR. MINTZER: Objection to form.</p> <p>10 THE WITNESS: So there is something that</p> <p>11 I disagree with in his statement. He said that</p> <p>12 triamcinolone is associated with smaller particles</p> <p>13 than Depo-Medrol.</p> <p>14 If you look at the two best articles on</p> <p>15 this, one by Benzon and one by Derby, that's not</p> <p>16 true. They come up with conflicting conclusions,</p> <p>17 but what there is consensus about is that</p> <p>18 triamcinolone aggregates at a much greater rate</p> <p>19 than Depo-Medrol.</p> <p>20 Because -- and this is based on the, you</p> <p>21 know, the FDA, you know, Multispecialty Working</p>
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<p>1 these are from, you know, contracts that the, that</p> <p>2 the university has that are way above my pay grade.</p> <p>3 BY MR. KIRBY:</p> <p>4 Q. If Dr. Bhambhani had checked to see if</p> <p>5 NECC was licensed, licensed in Maryland or</p> <p>6 Massachusetts, what would she have found?</p> <p>7 A. NECC was licensed in both states.</p> <p>8 Q. I think you were asked a question several</p> <p>9 hours ago about whether Dr. Bhambhani intended to</p> <p>10 inject these patients intrathecally. Is it</p> <p>11 possible for drugs that are even intended to be</p> <p>12 injected epidurally to go intrathecally?</p> <p>13 A. It definitely is, and it's not a rare</p> <p>14 event.</p> <p>15 Q. Are you -- you mentioned Dr. Saberski.</p> <p>16 Are you familiar with the Plaintiffs' expert,</p> <p>17 Dr. Saberski?</p> <p>18 A. Dr. Saberski, you know, doesn't really</p> <p>19 attend, you know, meetings. I know he doesn't</p> <p>20 review for the journals that I'm an editor of, so I</p> <p>21 have, I have never met him, but I know who he is.</p>	<p>1 Group Safety Guidelines. Because injection of Depo</p> <p>2 steroids into small arteries that feed the spinal</p> <p>3 cord has been responsible for probably a hundred</p> <p>4 cases of death or paralysis, and this is the basis</p> <p>5 for their recommendation, since triamcinolone</p> <p>6 aggregates more than Depo-Medrol, you can conclude</p> <p>7 by deductive reasoning that triamcinolone has a</p> <p>8 higher risk of complications.</p> <p>9 There's one randomized study that</p> <p>10 actually compared Depo-Medrol to triamcinolone, and</p> <p>11 it found that Depo-Medrol was better.</p> <p>12 So if you consider, you know, a higher</p> <p>13 risk and possibly lower effectiveness, you could</p> <p>14 say, Why would anyone use triamcinolone?</p> <p>15 BY MR. KIRBY:</p> <p>16 Q. So despite, despite that criticism, the</p> <p>17 fact that you, I guess as a pain physician, don't</p> <p>18 agree with him personally, do you believe he</p> <p>19 breached, that he's breaching the standard of care</p> <p>20 by using triamcinolone?</p> <p>21 MR. ROTH: Objection.</p>

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<p>1 transcript, do you know whether he has any evidence 2 whatsoever to show that the customers of NECC 3 ordered drugs using patient-specific prescriptions 4 are any different than Dr. Bhambhani? 5 MR. ROTH: I'm sorry. Mr. Kirby, I just 6 didn't get that question. Either it can be read 7 back, or can you repeat it? 8 MR. KIRBY: Sure. I'll try. 9 BY MR. KIRBY: 10 Q. So what I said is in reviewing 11 Dr. Saberski's deposition, do you know whether he 12 had any evidence whatsoever to show that any of 13 those customers of NECC were actually, had used 14 patient-specific prescriptions when ordering from 15 NECC? 16 A. I -- he has no evidence that the ordering 17 practices of the 75 other doctors were any 18 different from those of Dr. Bhambhani. 19 Q. Okay. And then you were asked -- I 20 swear, it's my last question. You were asked a 21 question by Mr. Roth a second ago about rigorous</p>	<p>1 reading and signing of the transcript was not 2 waived.) 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21</p>
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<p>1 inspections from the FDA. Despite the rigorous 2 inspections of manufacturers, do they still have 3 problems? 4 MR. ROTH: Objection to form. 5 THE WITNESS: Yes. I think, as we 6 discussed, FDA approved manufacturers, including 7 those of steroids such as Pfizer, have had their 8 share of problems in the past. 9 MR. KIRBY: Thank you so much. Those are 10 all of the questions I have, Doctor. Are we good? 11 Do you guys want to order? 12 MR. ROTH: Doctor, thank you very much. 13 MR. MINTZER: Nothing further. 14 MR. KIRBY: Do you guys want to order any 15 transcripts or what? 16 MR. MINTZER: I would like an E-tran, 17 please. 18 MR. KIRBY: That's Glenn. 19 MR. ROTH: Okay. Me too. 20 (Whereupon, the deposition of Steven Paul 21 Cohen, M.D. was concluded at 4:33 p.m., and the</p>	<p>1 Arnetta, et al v. BHSC, et al 2 Steven Paul Cohen, M.D. 3 INSTRUCTIONS TO THE WITNESS 4 Please read your deposition over 5 carefully and make any necessary corrections. You 6 should state the reason in the appropriate space on 7 the errata sheet for any corrections that are made. 8 After doing so, please sign the errata 9 sheet and date it. 10 You are signing same subject to the 11 changes you have noted on the errata sheet, what 12 will be attached to the deposition. 13 It is imperative that you return the 14 original errata sheet to the deposing attorney 15 thirty (30) days of receipt of the deposition 16 transcript by you. If you fail to do so, the 17 deposition transcript may be deemed to be accurate 18 and may be used in court. 19 20 21</p>